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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,706	04/16/2002	Camilo Anthony Leo Selwyn Colaco	8830-23	7593

7590 05/25/2006

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/049,706

Applicant(s)

COLACO, CAMILO ANTHONY  
LEO SELWYN

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants amendment filed May 5, 2006 has been received and entered. Claims 18-19 have been cancelled. Consequently, claims 1-17 and 20-23 are pending in the instant application, of which claims 1-13 and 20-22 have been withdrawn from further consideration as being drawn to a non-elected invention.

This application contains claims 1-13 and 20-22 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. The rejection of claims 14-17 and 23 under 35 U.S.C. 102(b) as being anticipated by Tunnacliff et al is maintained.

Applicants are asserting that the teachings of Tunnacliffe in relation to the utility of the disclosed stabilization method as applied to vaccine compositions is restricted solely to cell storage. Applicants further assert that at no time did Tunnacliffe or any of the other inventors recognize that inducing trehalose within the cell would make a cell more immunogenic. Applicants further assert that there is no suggestion that any intermediate stage cells would actually have utility as a vaccine. Applicants finally

assert that the Example 7 preparation does not contain an adjuvant, and therefore does not anticipate claim 16.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that the teachings of Tunnacliffe in relation to the utility of the disclosed stabilization method as applied to vaccine compositions is restricted solely to cell storage. However, it has long been held that a reference must be evaluated in its entirety, not on the basis of its preferred embodiments or working examples. *In re Mills*, 470 F.2d 649, 651, 176 (USPQ 198 (CCPA 1972)

Second, Applicants assert that at no time did Tunnacliffe or any of the other inventors recognize that inducing trehalose within the cell would make a cell more immunogenic, or have utility as a vaccine. However, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Finally, Applicants assert that the Example 7 preparation does not contain an adjuvant, and therefore does not anticipate claim 16. However, Applicants are respectfully directed to Example 7, in which the cell pellets were suspended in sodium carboxymethyl cellulose. (See column 18, lines 14-17). Carboxymethyl cellulose has adjuvant properties. (See US Patent Number 3,948,928, summary). Accordingly, each and every limitation has been addressed.

Tunnacliff et al (WO 98/24882) disclose of a vaccine composition comprising a prokaryotic cell, which contains at least 10 mM of trehalose within the cell. (See pages 6, 13, 21 and claims).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 14-17 and 23 under 35 U.S.C. 102(e) as being anticipated by Tunnacliff et al (US Patent 6,468,782) is maintained.

Applicants assertions are identical to those recited above in paragraph number 1, and have been fully addressed in paragraph number 1.

Accordingly, this rejection is maintained for reasons of record, as well as the reasons set forth above in paragraph number 1.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 14-17 and 23 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained.

Applicants are asserting that the specification clearly defines "prokaryotic cell"

(page 4, line 30-page 5, line 2). Applicants further assert that the specification also discloses of several examples of prokaryotic cells useful in the invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants have asserted that the term prokaryotic cell is well defined and examples of prokaryotic cells are specifically recited. This statement is not argued by the Examiner. However, Applicants are respectfully directed back to their own claim language which recites... "A vaccine composition comprising a prokaryotic cell **or cell residue of a prokaryotic cell...**" (Emphasis added). It is precisely this limitation which does not meet the written description guidelines. For instance what identifiable structure can be discerned from a cell residue? Similarly what activity would this residue have? *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number** of molecules, usually defined by a

nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” (Emphasis added).

Claims 14-17 and 23 recite a prokaryotic cell or cell residue of a prokaryotic cell which has been treated to increase the concentration of trehalose therein without subsequent drying of the cell in the presence of a non-reducing carbohydrate..

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a “cell residue of a prokaryotic cell” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that “applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number** of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." (Emphasis added).

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.



**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
May 15, 2006